GENERIC SUB-STUDY SUBMISSION – 0925-0046

DATE OF REQUEST: 3/2/2011

SUB AGENCY (I/C): NIH/NCI/DCTD/CTE

TITLE OF SUB-STUDY: Survey to Determine IRB Policy Regarding NCI Action Letters

GENERIC CLEARANCE UNDER OMB #0925-0046-**09** ***EXP. DATE:*** *02*/28/2013

TOTAL ANNUAL BURDEN APPROVED:	7050 hours
BURDEN APPROVED TO DATE:	1691 hours
BURDEN THIS REQUEST:	50 hours

ABSTRACT:
In the past several years, the Cancer Therapy Evaluation Program (CTEP), which funds/oversees Phase 2 and 3 treatment trials conducted by NCI's extramural Cooperative Groups, has focused on operational efficiency in such areas as collapsing timelines for the development, implementation and completion of trials. One major area of concern is increasing the number of patients accrued to trials so that research will lead directly to new and improved treatments in cancer. Over 2000 sites across the country conduct CTEP trials. We have anecdotal information that the Institutional Review Boards (IRBs) at some of these sites are incorrectly interpreting OHRP policy regarding CTEP Action Letters and therefore inadvertently inhibiting patient accrual at their sites. CTEP issues an Action Letter when new or modified risk information necessitates changes to the protocol and/or informed consent document (ICD). The requested changes can be minor or major. We plan to survey institutions to determine how widespread this occurrence is. If this is occurrence is widespread then the numbers of patients accrued nationally is being impacted and NCI will need to develop a strategy to address it. Survey participants will consist of two individuals, the IRB Chair and the IRB Director, at approximately 300 extramural clinical research sites (cancer centers, community hospitals, academic medical centers). They will receive an email with a link to Survey Monkey and asked to respond to 5 questions. The collaborative effort includes representation from the Cooperative Groups, Cancer Centers, and other NCI Programs and Divisions.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?
_____YES __X___NO_____N/A

OBLIGATION TO RESPOND:
__X___ VOLUNTARY
_____ REQUIRED TO OBTAIN OR RETAIN BENEFITS
_____ MANDATORY

HOW WILL THIS SURVEY BE OFFERED?
__X__ WEB SITE
__ ___TELEPHONE INTERVIEW
_____ MAIL RESPONSE
_____ IN PERSON INTERVIEW
_____ OTHER: __ _____

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GENERIC SUB-STUDY SUBMISSION – 0925-0046

DATE OF REQUEST: 3/7/11

SUB AGENCY (I/C): NIH/NCI/DCTD/CIP

TITLE OF SUB-STUDY: NCI Cancer Research Imaging Camp

GENERIC CLEARANCE UNDER OMB #0925-0046-**10** ***EXP. DATE:*** *02*/28/2013

TOTAL ANNUAL BURDEN APPROVED:	7050 hours
BURDEN APPROVED TO DATE:	1691 hours
BURDEN THIS REQUEST:	17 hours

ABSTRACT:

The National Cancer Institute supports an annual educational opportunity entitled "NCI Cancer Research Imaging Camp". The goal of this 6-day, intensive training course is to educate early career-level cancer scientists in the specifics of *in vivo* imaging modalities. Through lectures and hands-on laboratory sessions, participants gain experience with a wide range of imaging modalities, including advanced optical imaging, MRI, PET, SPECT, CT, and ultrasound. After the completion of this course, participants should be able to select and apply the appropriate *in vivo* imaging techniques necessary to investigate a biological hypothesis and to interpret the resulting imaging data.

The NCI Cancer Research Imaging Camp was first offered in 2007, and has been offered each year since. The participants will be former and new students who have completed the NCI Research Imaging Camp. Approximately 25 students attend this course each year. To ensure that the Camp is successfully meeting its goals, we are requesting approval to contact the students who have completed the course and ask them a few questions pertinent to their abilities to integrate *in vivo* imaging into their current research.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?
_____YES __X___NO_____N/A

OBLIGATION TO RESPOND:
__X___ VOLUNTARY
_____ REQUIRED TO OBTAIN OR RETAIN BENEFITS
_____ MANDATORY

HOW WILL THIS SURVEY BE OFFERED?
__X__ WEB SITE
__ ___TELEPHONE INTERVIEW
_____ MAIL RESPONSE
_____ IN PERSON INTERVIEW
_____ OTHER: _____

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